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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

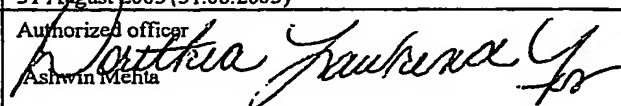
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 17 OCT 2005

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Applicant's or agent's file reference 27060	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/IL04/00047	International filing date (day/month/year) 15 January 2004 (15.01.2004)	Priority date (day/month/year) 16 January 2003 (16.01.2003)	
International Patent Classification (IPC) or national classification and IPC IPC(7): C12N 15/82, 15/83, 15/87, 15/90 and US Cl.: 800/278, 285, 286			
Applicant BIO-OZ ADVANCED BIOTECHNOLOGICAL			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) ___, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 09 August 2004 (09.08.2004)		Date of completion of this report 31 August 2005 (31.08.2005)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer  Ashwin Mehta Telephone No. 571-272-1600	

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/IL04/00047

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
pages 1-23 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the claims:
pages 24-26 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the drawings:
pages 1 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/IL04/00047

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 6-25

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 22-25 are so unclear that no meaningful opinion could be formed (*specify*):

The claims attempt to limit a method of previous claim 21. However, claim 21 is directed to a product, not a method.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 6-21

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL04/00047**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>3, 5</u>	YES
	Claims <u>1, 2, 4</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-5</u>	NO
Industrial Applicability (IA)	Claims <u>1-5</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1, 2, and 4 lack novelty under PCT Article 33(2) as being anticipated by Brignetti et al. or Voinnet et al.

Brignetti et al. teach the suppression of silencing of a GFP transgene in transgenic *Nicotiana benthamiana* plants that were mechanically inoculated with potato virus Y, cucumber mosaic virus, or recombinant PVX-PVY or PVX-CMV vectors. Viruses systemically infected the plants (pages 6739-6743). Voinnet et al. teach the suppression of silencing of a GFP transgene in transgenic *Nicotiana benthamiana* plants that were mechanically inoculated with a variety of plant viruses. The viruses systemically infected the plants (pages 14148-14151).

Claims 3 and 5 lack an inventive step under PCT Article 33(3) as being obvious over Brignetti et al. or Voinnet et al. in view of Karasawa et al. Gal-On et al.

Brignetti et al. and Voinnet et al. are discussed above.

Brignetti et al. and Voinnet et al. do not teach avirulent viruses or viral inoculation using an inoculation gun.

Karasawa et al. teach avirulent strains of CMV (pages 1186-1190).

Gal-On et al. teach a method of inoculating plants with plant viruses using particle bombardment. Gal-On et al. assert that bombardment technology is 10^6 -fold more effective than mechanical inoculation (pages 3223-3226).

It would have been obvious and within the scope of one of ordinary skill in the art to modify the method of increasing expression of a silenced transgene in plants of Brignetti et al. or Voinnet et al., by inoculating the plants with an avirulent virus, such as the avirulent CMV strains taught by Karasawa et al. One would have been motivated to do so, as the virus would not cause systemic disease symptoms in the host plant. It would also have been obvious to modify the method by using the particle bombardment method of Gal-On et al. to inoculate the plants. One would have been motivated to do so, as Gal-On et al. teach that it is more efficient than mechanical inoculation.

Claims 1-5 the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NEW CITATIONS

NONE

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/IL04/00047

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 4 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: the claim does not end with a period punctuation mark.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/IL04/00047

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-5 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1 and 3 are indefinite for the following reason(s):

In claim 1: the recitation, "an expression" renders the claim indefinite. The article, "an" suggests that there is more than one type of expression. However, it is not clear what other types of expression of polynucleotide sequences are being referred to. In claim 1: the recitation, "selected capable of" renders the claim indefinite. The recitation is confusing, and its meaning is not exactly clear.

In claim 3: the recitation, "avirulent virus" renders the claim indefinite. It is unclear exactly when a virus is to be considered avirulent. Page 10 of the description states, "Preferably, the virus is avirulent and this is incapable of causing severe symptoms, such as reduced growth rate, mosaic, ring spots, leaf roll, yellowing, streaking, pox formation, tumor formation and pitting." However, the recitation, "severe" is a relative term that has not definite meaning. It is unclear when a symptom should not be considered "severe." While examples of severe symptoms are provided, this list is incomplete, as indicated by the recitation, "such as". It is unclear what other symptoms are to be considered severe.